Regulating Controversial Programs for Unpopular People: Methadone Maintenance and Syringe Exchange Programs

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ABSTRACT

One third of all cases of the acquired immunodeficiency syndrome (AIDS) in the United States are associated with the injection of illicit drugs. There is mounting evidence for the effectiveness of syringe exchange programs in reducing human immunodeficiency virus (HIV) risk behavior and HIV transmission among injection drug users. Expansion of syringe exchange would require increased public funding and undoubtedly would include government regulation of syringe exchanges. An analogy is drawn with the present system of regulation of methadone maintenance treatment programs and possible regulation of syringe exchange programs. Specific recommendations are offered to reduce the likelihood of repeating the regulatory problems of methadone maintenance treatment in future regulation of syringe exchange programs. (*Am J Public Health.* 1995;85:1577–1584)

Introduction

The misuse of psychoactive drugs creates truly enormous health problems in the United States, of which the acquired immunodeficiency syndrome (AIDS) is the most recent critical example. Developing public policies to reduce the negative health consequences of psychoactive drug use is a formidable challenge.[1] One of the problems in the United States has been the relative lack of historical analyses in the formulation of policies on psychoactive drug use. Musto[2] and Courtwright,[3,4] in particular, have been critical of the lack of historical analysis in the development of drug policies.

Drawing constructive parallels between historical situations and current health and drug policy questions is, of course, never easy. In this paper, we present evidence for a strong historical analogy between public regulation of methadone maintenance treatment programs—where the critical policy decisions were made 25 years ago—and public regulation of syringe exchange programs—where the decisions are being made currently. It is hoped that many of the mistakes made in implementing and regulating methadone maintenance programs can be avoided in the case of syringe exchange programs.

AIDS and Injection Drug Use in the United States

The United States has the world's largest problem of human immunodeficiency virus (HIV) infection among injection drug users. Injection drug use has been associated with more than 125 000 cases of AIDS in the United States,[5] an amount representing over one third of total nationwide cases to date and more than the total number of cases—including both those related to injection drug use and all other cases—in any other industrialized country. Recent estimates indicate that injection drug use is now associated with a plurality of new HIV infections in the United States.[6]

Despite continuing controversy,[7–10] there has been increasing support for legal access to sterile injection equipment for injection drug users in the United States. Major reviews conducted by the National Commission on AIDS,[11] the US General Accounting Office,[12] and the Institute for Health Policy Studies of the University of California at San Francisco[10] all concluded that syringe exchange is a promising method for reducing HIV transmission in the United States. Recently published results from long-term studies with large samples of injection drug users in San Francisco[13] and New York[14] provide additional evidence for the effectiveness of syringe exchanges in reducing HIV risk behavior. In 1992, Connecticut repealed its law requiring prescriptions for the sale of injection equipment, so injection drug users in that state may now purchase and possess sterile injection equipment.[15] A

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Note. The views expressed in this paper do not necessarily reflect the positions of the American Foundation for AIDS Research or of the institutions by which the authors are employed.

Editor's Note. See related annotation by Coutinho (p 1490) in this issue.

TABLE 1—The Development of Methadone Maintenance (1960s and 1970s) and Syringe Exchange (1980s and 1990s) in the United States

Components	Methadone Maintenance	Syringe Exchange
Context	Heroin epidemic[36]	HIV/AIDS epidemic among injection drug users[5,6]
Staff	Legally harassed, highly committed, strong sense of accomplishment[17,18]	Often legally harassed, highly committed (many are volunteers), strong sense of accomplishment[10]
Attitudes toward research	Developed by researchers, implemented with evaluation studies	Generally supportive, usually implemented with evaluation studies
Research findings	Strongly supportive[37]	Strongly supportive[7,10–14]
Participant response	Accomplishment and gratitude[17,18]	Accomplishment and gratitude[10]
Controversy	Challenged abstinence from narcotic drugs as only legitimate goal[18]	Challenged abstinence from illicit drugs as only legitimate goal[7–13]

recent public opinion poll shows that a majority of the US population now supports syringe exchange programs as a method for reducing HIV transmission.[16]

Most important, there has been very rapid growth in the number of syringe exchange programs in the United States. There were 33 programs in the nation in the fall of 1993, when the University of California at San Francisco report[10] was compiled. As of January 1995, there were at least 68 syringe exchange programs in the United States (D. Purchase, North American Syringe Exchange Network, written communication).

Maintenance of the current numbers of syringe exchange programs in the United States will probably require some form of public funding (local, state, or federal), because current levels of private support for exchanges will probably not last indefinitely. Moreover, further expansion of syringe exchanges—to the point where syringe exchange programs might reach their potential effect on reducing HIV transmission at the national level—will almost certainly require additional public funding.

Public funding for syringe exchange programs raises appropriate questions about regulating the operation of the programs and expenditure of the public monies. To our knowledge, all US syringe exchange programs that currently receive public funds are regulated through some mechanism: they are directly operated by health departments, operated under contracts with health departments, or operated under explicit regulatory guidelines issued by health departments. Other programs (in Connecticut, Hawaii, and New York) do not receive public funding but are nonetheless subject to legal regulation.

Accountability for expenditure of public funds is a very appropriate concern for government, and we expect that most syringe exchange programs in the United States will continue to be subject to some form of public regulation. Public regulation of syringe exchange programs is likely to be both inevitable and an important determinant of the extent to which the programs are able to fulfill their public health mission of reducing HIV transmission.

We examine here some of the potential critical issues in regulating syringe exchanges in the United States. As a guide for this analysis, we draw upon a potentially instructive parallel with the public regulation of methadone maintenance treatment for heroin addiction over the past 30 years in the United States (for a description of the development of methadone maintenance and its regulation, see Dole[17,18] and Institute of Medicine[19,20]). The analysis also draws upon our experience with evaluations of syringe exchanges in Europe, Australia, and the United States (for a review of our publications, see Lurie et al.[10]), with particular reliance on our ongoing evaluation of the syringe exchange programs in New York City. (The New York City exchanges are operated by community-based 501 (C) 3 not-for-profit organizations with funding from the American Foundation for AIDS Research and New York State, and with regulation by the New York State Health Department's AIDS Institute.)

The Methadone Maintenance/Syringe Exchange Regulation Analogy

Table 1 presents some of the strong similarities between the initial development of methadone maintenance treatment and that of syringe exchange programs in the United States. A particularly important similarity exists with respect to staffing. The originators of methadone maintenance were legally harassed—Dole and Nyswander were threatened with loss of their medical licenses[18]—but the staffs of methadone maintenance treatment programs in those early years were generally very optimistic about their work and had a strong sense of accomplishment. Similarly, some staff members of recent US syringe exchange programs have actually been arrested—although they have usually been able to mount successful "public health necessity" defenses—yet the staffs of such programs generally are also quite optimistic about their work and have a strong sense of accomplishment. Moreover, just as staff morale and the gratitude of methadone maintenance patients for receiving treatment had reinforced each other in the early years, the same cycle of positive reinforcement between staff and participants appears to exist today in syringe exchange programs.[21]

Both methadone maintenance treatment and syringe exchange programs can also be seen as applications of the "harm reduction" perspective to the problems of psychoactive drug use.[22,23] Both methadone maintenance and syringe exchange programs attempt to reduce specific harms associated with drug use (e.g., the chaotic life-style associated with addiction to illicit heroin and the transmission of HIV through shared injection equipment) without requiring abstinence from all psychoactive drug use.

The similarities in the development of methadone maintenance and syringe exchange noted in Table 1 are important but can also be considered merely "surface" similarities. There are, however, two other points of similarity—implicit in the title of this paper—at a "deeper" level.

First, methadone maintenance and syringe exchange programs are controversial because of differences in scientific interpretations of the relevant evaluation

research and, even more so, because such programs contradict the "antidrug" symbolism in public discourse in the United States. If "drugs are all bad," should the government ever help fund the provision of a strong narcotic drug to persons with a history of drug addiction? Likewise, should the government ever pay to provide the means to inject drugs?

From our experience in debates on both methadone maintenance and syringe exchange, we suggest that supporting methadone maintenance treatment or syringe exchange often requires adopting a new outlook for assessing harmful effects of psychoactive drug use. That is, one must move from an "all drug use is bad" stance to a "some drug use is much worse than other drug use" perspective.

The second "deeper" similarity between methadone maintenance treatment and syringe exchange is that they are health services for persons who are often poor, relatively powerless, and highly stigmatized in American society. Persons who use illicit drugs are often seen as deserving punishment rather than deserving health care, even if punishment (incarceration) is not likely to be effective—and if failure to provide health services to drug users endangers the health and well-being of the community as a whole.

A corollary of this stigmatization is the belief that drug users cannot be trusted to use health services appropriately, that they will manipulate the service providers to achieve illegitimate ends. Thus, in this view, the services must be provided in a highly controlling manner in order to prevent such illegitimate manipulations.

There are also, of course, many important differences between methadone maintenance treatment and syringe exchange programs. The theory of methadone maintenance treats narcotic addiction as a disease. Methadone is seen as a powerful medication for the treatment of that disease that should be used only under medical supervision. Conversely, syringe exchange programs assume that injection drug users (even those who are addicted to psychoactive drugs) are capable of practicing safer injection and that syringe exchange participants do not require supervision in order to avoid HIV infection.

Methadone maintenance and other drug treatment programs have also been criticized as a form of maintaining social control over heroin users,[24] and this criticism has not (yet) been made of syringe exchange programs. It is interesting to note, however, that many of the "social control" aspects of methadone maintenance treatment are related to official regulations rather than to the medication itself. Having to take the medication while being observed at the clinic and having to obtain permission from the federal government to take a 3-week vacation are examples of social controls arising from the regulations.

The analogy between methadone maintenance treatment and syringe exchange programs should thus be seen only as a strong analogy and not as a complete parallel. We do believe, however, that this analogy can be particularly helpful when considering the public regulation of syringe exchange programs.

TABLE 2—The Status of Methadone Maintenance in the 1990s in the United States

Components	Status
Context	Shortages of treatment capacity in comparison with number of persons desiring treatment
Staff	Debate over greater need for more treatment capacity vs expanding services within present programs; sense of accomplishment undermined by bureaucracy, paperwork, and new problems of cocaine use and HIV infection among patients
Attitudes toward research	Generally supportive
Research findings	Continue to be strongly supportive[19,20,38]
Participant response	Mixed; gratitude and accomplishment, but also negative attitudes toward clinic rules, inconvenience, and so forth, as well as methadone itself (e.g., "gets in your bones")[39]
Controversy	Continues, along with racial antagonisms, stigmatization of patients, and "not-in-my-backyard" public attitudes[17–19]

Current Status of Methadone Maintenance Treatment

As noted in Table 2, the potential impact of methadone maintenance on the problem of heroin addiction in the United States is still far from being realized. A full analysis would include lack of funding for adequate treatment capacity,[19,20] underfunding of currently funded methadone maintenance treatment programs,[19,20] inadequate dosages of medication for many patients,[25] and increasing polydrug use among persons addicted to heroin.[26] Such an analysis is beyond the scope of this paper, but it is important to note the role of government regulations in methadone treatment.

History of Methadone Regulations

Current government regulation of methadone maintenance treatment reflects both conflict between two long-standing frameworks for regulating psychoactive drug use in the United States and the particular situation in the late 1960s and early 1970s when methadone was first formally approved as a treatment for heroin addiction. Despite more than 25 years of experience in providing methadone maintenance treatment, there have been relatively few changes since the regulations were first promulgated in 1972.[19,20]

The 1906 Pure Food and Drug Act implemented federal regulation of medicines, including how they would be labeled and dispensed. This act, authorized under the interstate commerce provisions of the constitution, has been amended on several occasions. Within this regulatory framework, a medication could not be given to patients until it had been approved by the Food and Drug Administration. Approval of a medication was given in terms of its specific uses (clinical purposes). However, research on using a medication for purposes other than the officially approved purpose was also permitted. Indeed, it has been and still is common that physicians prescribe ap-

proved medications for purposes other than the officially approved use of the medication. Within this regulatory framework, then, methadone was approved as an analgesic and antitussive in 1947.

The 1914 Harrison Narcotic Act, upheld by the Supreme Court in 1918, criminalized nonmedical distribution and possession of certain psychoactive drugs, including heroin. (The state of being addicted to an illegal drug, however, was not in itself a crime.) This act was authorized under the tax provisions of the constitution, and enforcement was delegated to the Bureau of Narcotics within the Treasury Department. The Bureau of Narcotics took the position that prescribing long-term provision of narcotic drugs to narcotic addicts was not medical treatment; rather, it was the equivalent of drug trafficking. In the 1920s, the Bureau of Narcotics caused the closure of all of the clinics in the United States that had been prescribing morphine as a maintenance treatment for narcotic addicts. This was done without any court test of whether or not maintenance treatment could be considered legitimate medical treatment.

Illicit narcotic use continued in the United States after the passage of the Harrison Act and closure of the morphine maintenance clinics. World War II somewhat disrupted heroin supplies to the United States, but after the war both supplies and use increased. This increase in heroin use began in the 1950s in New York City and then spread to become a nationwide epidemic in the late 1960s.

Dole and Nyswander, working in New York City, developed oral methadone maintenance treatment for heroin addiction in the early and middle 1960s. The theory underlying methadone maintenance was that some heroin addicts had consumed sufficient quantities of narcotics to cause an irreversible change in their biochemistry. Thus, they could not function "normally" in the absence of narcotics. Because it was both long acting and slow acting, methadone could be administered to these addicts without causing either the euphoria of rapid drug uptake or the acute abstinence symptoms of drug withdrawal. Moreover, because of the cross tolerance between different types of narcotic drugs, persons maintained on moderate to high levels of methadone also would not be able to feel the euphoric effects of heroin (in the event that they used it). The early research results and subsequent studies showed methadone maintenance treatment to be quite effective in reducing heroin use.[17–20,26]

While Dole and Nyswander were developing methadone maintenance, Treasury Department officials told them that prescribing a narcotic for maintenance was illegal. Dole and Nyswander continued their work anyway, essentially challenging the Bureau of Narcotics to take them to court over the issue. In their opinion, they were conducting legitimate research with a drug that had already been approved by the Food and Drug Administration (although, of course, not for the purpose of narcotic maintenance treatment). The Bureau of Narcotics did not pursue the matter.

As information about the effectiveness of methadone maintenance spread in the early and late 1960s, others began providing this type of treatment. This was usually done under research auspices, with an "investigational new drug" approval from the Food and Drug Administration. While the record-keeping requirements for the investigational new drug procedures were followed, it was also clear that most of these investigational drugs were serving as treatment provision rather than merely as research programs.

In the late 1960s and early 1970s, there were multiple concerns about the use of methadone maintenance treatment for heroin addiction. First, the heroin epidemic was perceived as a national emergency, whereby not only was methadone maintenance needed, but many persons also believed that it was impractical to go through the normal Food and Drug Administration process by which methadone (an already approved drug) would have then had to be approved for the new use of narcotic maintenance treatment. Second, there was opposition to methadone treatment as simply substituting one drug for another. Third, there was concern that methadone would be diverted from medical treatment into an illicit market, as well as concern that most heroin addicts needed other services in addition to methadone medication. Finally, there was a willingness among some drug treatment providers to use methadone as a method to attract heroin addicts into treatment, but without these providers having accepted Dole and Nyswander's underlying theory. Thus, these providers were willing to prescribe methadone only for limited time periods and only at dosages substantially lower than what Dole and Nyswander considered adequate.

Federal approval of methadone as a medication for maintenance treatment was officially provided in 1972, but methadone maintenance treatment could be provided only in accord with the Food and Drug Administration regulations issued at that time. In sharp contrast to all other medications that physicians are permitted to prescribe in the United States, these regulations contained many restrictions on how the medication could be used. Among the restrictions were the following. Methadone maintenance could be provided by approved programs but not by individual practitioners. Counseling and rehabilitative services were required in addition to the provision of maintenance medication. Most medication had to be taken at the program site, and there were strict requirements for granting (and rescinding) "take home" medication. A documented history of narcotic addiction was required for eligibility to receive treatment. Additional documentation was needed to receive high dosages (more than 100 mg/day), and patients at high dosages could not receive take home medication.

In addition to the federal regulations, state and local governments could also establish regulations for methadone maintenance treatment. These state and local regulations could be more restrictive, but could never be less restrictive, than the federal regulations. Thus, many state regulations today are substantially more restrictive, and there have been relatively few changes in the original federal regulations since they were initially issued.[19]

Counterproductive Aspects of Methadone Regulations

Methadone maintenance treatment has undoubtedly reduced illicit heroin use for hundreds of thousands of addicts in the United States.[19,27] Nevertheless, the current highly restrictive, multiple sets of regulations for methadone maintenance treatment in the United States both reflect and exacerbate the problems of such treatment.[19,27,28]

The restrictions on who may provide methadone maintenance, the multiple services to be provided, the length of time one may receive methadone maintenance (in some state regulations), and eligibility for methadone maintenance all serve to reduce the numbers of heroin addicts who actually receive methadone maintenance. This, in turn, increases the street demand and the pressure for diversion of methadone from patients in treatment.

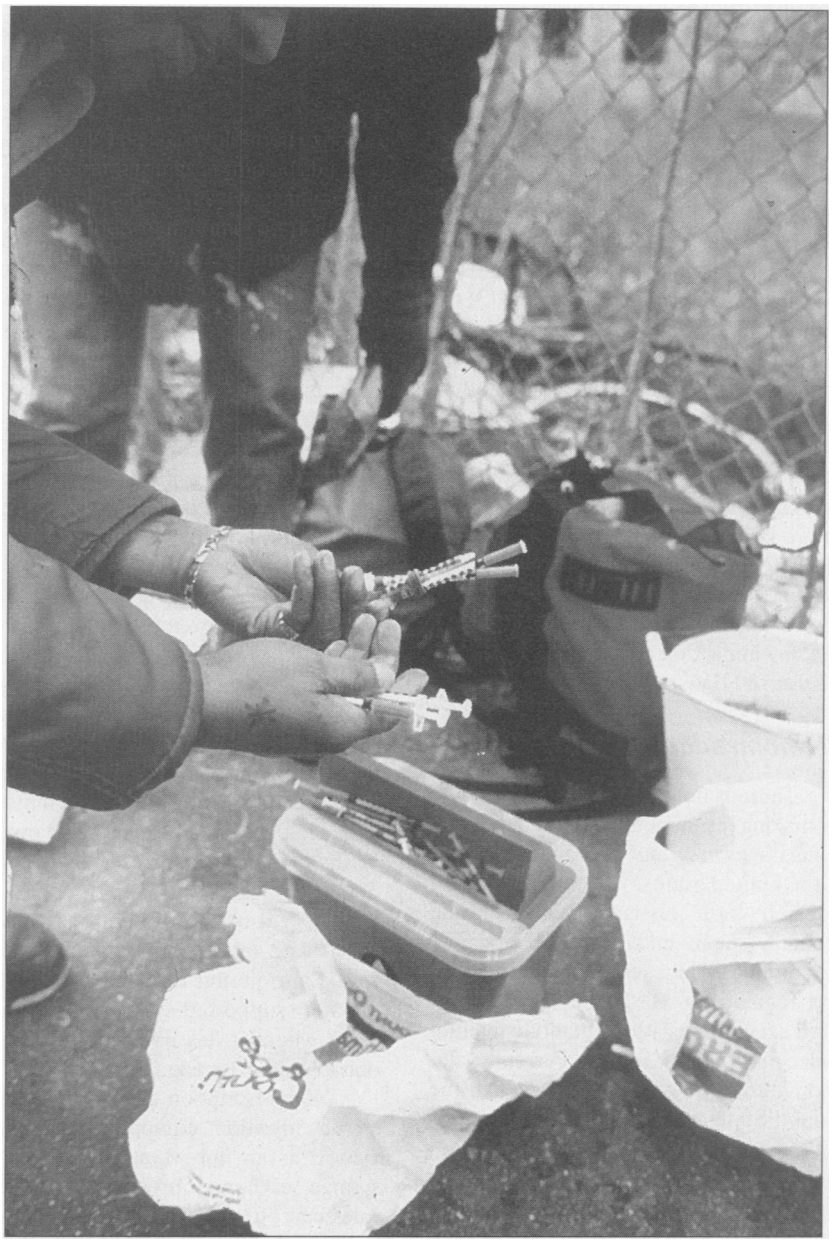
Another important effect of the regulations has been to increase the

administrative burdens ("paperwork") and to reduce the degree of autonomy in clinical decision making for providers of methadone treatment. Both of these factors reduce treatment staff morale.[29]

The highly restrictive regulations also serve to undermine patient morale in methadone treatment programs. The complexity and rigidity of the regulations work against the idea that treatment is individualized according to the needs of the specific patient.[30] The perceived punitive nature of many aspects of the regulations casts patients in the role of persons attempting to misuse the program. Such "altercasting" can become a self-fulfilling prophecy.

An additional counterproductive aspect of the regulations is that restricting the numbers of service providers has led to the emergence of relatively large program sites in many cities. A single site may provide services for several hundred methadone maintenance patients. The concentration of hundreds of patients—many of whom may have to attend daily (also due to regulations)—can lead to "loitering" problems and the creation of visible markets for diversion of methadone to heroin users not in treatment. The loitering and visible diversion problems can then lead to scapegoating of all methadone maintenance patients and further community and regulatory restrictions on both patients and service providers.

The Institute of Medicine has recently conducted an analysis of methadone regulations and concluded that "current policy . . . puts too much emphasis on protecting society *from* methadone and not enough on protecting society from the epidemics of addiction, violence and infectious diseases that methadone can help reduce."[19(p3)]



Underground needle exchange on the Lower East Side of Manhattan. Roving exchange is still conducted in the same manner. Photo by Alan Clear.

Regulation of Syringe Exchange Programs in the United States

Could the same types of restrictive regulatory problems that have limited methadone maintenance treatment also occur with syringe exchanges? To paraphrase the Institute of Medicine, could we develop regulations that "protect" society from syringe exchanges rather than protecting society from HIV infection?

As noted above, the restrictions on methadone maintenance treatment appear to have arisen from several different sources: simple opposition to methadone maintenance treatment; the complicated legal status of methadone when maintenance treatment was developed; concerns to limit possible diversion of medication to persons not enrolled in treatment; use of methadone treatment to achieve other goals (including abstinence from psychoactive drug use); and desires to maintain quality of treatment through requiring that additional services be provided.[27]

It appears to us that very similar factors will operate in the political decisions made with respect to regulations for syringe exchange programs. The context for implementing regulations also will be similar: continued social stigmatization of psychoactive drug users, continued controversy about the desirability of the services, and financial pressure. Several of the content areas for regulation of methadone treatment and syringe exchange programs are also quite similar: siting (where programs can be located), documenting eligibility for participation, "diversion" (of medication or injection equipment) to persons not officially enrolled in the program, and the provision of additional services to program participants.

There are at least two US examples of syringe exchange programs in which the regulations were so restrictive that the programs failed to achieve any impact on HIV transmission in the community. Both the first legal syringe exchange program in New York City[8,31] and the first legal program in Washington, DC,[32] were restricted as to (1) the sites where services could be provided, (2) who could use the services (i.e., only injection drug users awaiting entry into treatment), and (3) the numbers of syringes that could be exchanged per visit (only one in New York and three in Washington). In addition, both programs had very long entrance procedures (lasting several hours) in which receipt of other services, such as examinations for tuberculosis, was mandated. Because of these restrictions, neither program was able to attract large numbers of participants (only 270 in New York and 33 in Washington), and neither had any impact on communitywide transmission of HIV.

Recommendations

There is not yet a firm research base for making recommendations about operational issues in syringe exchange programs in the United States. Waiting until such a research base exists, however, would probably mean encoding bad practices into many syringe exchange operations and regulations. Based on the accumulated experience with methadone maintenance programs[19,20] and our current evaluation studies of syringe exchanges in the United States,[21,33–35] we offer the following guidelines to reduce the likelihood of the United States developing an overly restrictive—and therefore ineffective—system of syringe exchanges. We believe that these recommendations address the issues that are most likely to be controversial in formulating regulations for syringe exchange programs (aside from the very existence of the programs).

1. Syringe exchange will neither decimate local communities nor eradicate all HIV risk behavior. Mass media coverage of controversial programs like syringe exchange and methadone maintenance tends to highlight either extremely positive or extremely negative positions. This can lead to both exaggerated fears about hypothesized negative effects of the programs and unrealistic expectations about desired positive effects. Decisions about syringe exchanges need to be made with a candid and balanced awareness of both the strengths and limitations of syringe exchange as a method of reducing overall drug-use-related harm.

Syringe exchanges should be seen as a component of comprehensive systems to address the problems of drug abuse and HIV infection. In particular, exchanges need to be able to refer drug users to drug abuse treatment programs.

2. The present laws requiring prescriptions for the sale of injection equipment in some states and the laws criminalizing the possession of equipment for injecting illicit drugs should be repealed. The laws requiring prescriptions for dispensing of injection equipment and criminalizing the possession of injection equipment provide no discernible benefit in terms of reducing illicit drug use and, indeed, appear to contribute to multiperson use of HIV-contaminated injection equipment.[7,8,10–13,15] Even in instances in which syringe exchange programs have obtained legal exemptions from these laws, the laws can greatly complicate the programs' operation. If a drug user legally obtains a syringe from an exchange, should he or she be subject to arrest for the possession of the syringe? If a drug user obtains a syringe on the illicit market and is taking it to an exchange, should he or she be subject to arrest for possession of that syringe?

Repeal of the prescription requirements and injection paraphernalia laws would also permit the legal operation of privately supported syringe exchanges in areas where it has not been possible to obtain public funding.

Nonprescription pharmacy sales of sterile injection equipment should be viewed as an important complement to syringe exchange programs. Pharmacy sales can often reach drug injectors who cannot readily visit exchange programs and would also alleviate potential problems of drug users congregating around syringe exchange program sites if the programs were the only source of legal injection equipment.

3. It is important that regulations be flexible. Staff of current US exchanges are still learning how to operate exchanges. In contrast with what happened with the methadone regulations, regulations for syringe exchanges should be drafted with the idea that they will need frequent revision. Many current regulations of syringe exchange programs require programs to participate in evaluation research, which is to be commended. With additional experience and evaluation research, the knowledge base for operating exchanges should increase rapidly. An increased knowledge base will be of little value, however, if regulations are difficult to modify. Regulations that have been incorporated into formal legislation would, of course, be particularly difficult to modify.

4. Syringe exchanges need to maintain clarity as to their primary purpose, namely, to reduce HIV/AIDS risk behavior among injection drug users in the community. The original purpose of methadone maintenance was to provide indefinite chemotherapy to persons whose use of heroin had caused irreversible physiological changes. Many programs, however, were implemented to use methadone only as an intermediary step toward abstinence from all narcotic drug use. Some state regulations required this subversion of the original purpose of methadone treatment by setting time limits on such treatment. Provision of services in addition to basic syringe exchange, whether on-site or through referral, is undoubtedly a necessary component of a successful syringe exchange. Nevertheless, syringe exchanges should not compromise their primary goal of reducing HIV transmission by requiring drug injectors to participate in other services or by otherwise limiting the number of participants.

5. "Secondary distribution" of sterile injection equipment from syringe exchange participants to other injection drug users should be encouraged rather than discouraged. Many of the most restrictive aspects of current methadone regulations, such as requiring very frequent clinic attendance, are designed to reduce diversion of medication from patients to persons not enrolled in the programs. Methadone is a powerful medication, so there is a clear rationale for requiring medical supervision of its use. There is no comparable rationale for trying to control the distribution of sterile injection equipment.

Although there are likely to be real advantages to having injection drug users personally attend syringe exchanges, it is also important that these individuals be able to encourage each other to practice safer injection, through mutual education and through distribution of the means for safer injection. Attempts to "control" the behavior of injection drug users by making them attend the exchanges would violate the fundamental syringe exchange premise that injection drug users are capable of modifying their own behavior.

Whenever possible, laws that require prescriptions for dispensing sterile injection equipment and laws that criminalize

the possession of injection equipment should be repealed as part of formal authorization of syringe exchanges.[11] Having different legal statuses for injection equipment obtained from a syringe exchange and equipment obtained from other sources will not reduce illicit drug injection, may contribute to HIV transmission, and will pose a complex, nonproductive task for law enforcement.

6. Discretion is an important part of valor. Syringe exchange sites need to be located where drug injectors can access them conveniently; this will often be in areas where drugs are sold. Siting decisions should, however, give preference to multiple sites, long hours of operation, and the provision of private spaces for meetings of injection drug users. As noted earlier, the restrictive regulations on methadone programs have often led to large numbers of patients frequently attending a single site, followed by visible congregations of patients in the area and intense community relations problems. While drug users have not necessarily forfeited their constitutional right to freedom of assembly, it would still be wise to locate sites and schedule hours of operation in such a way as to minimize visible congregations of drug users near syringe exchange programs.

7. Regulations should support rather than undermine the clinical capacities of syringe exchange staff. As noted earlier, methadone treatment regulations often restrict clinical decision making by treatment program staff, leading to staff morale problems. Syringe exchange staff have "clinical" tasks in terms of developing trusting relationships with injection drug users, providing certain services on-site, and making referrals for other services. Exchange staff need to be able to treat exchange participants as individuals. The ability of exchange staff to conduct clinical work can be enhanced by requiring a minimum of administrative paperwork and providing sufficient funding for other services, but also by mandating a minimum of services that must be provided to all exchange participants.

8. Finally, and perhaps of greatest importance, the participants in the exchanges should be treated with dignity. This goes beyond the need for "user-friendly" services. From our observations to date, the power of syringe exchanges to alter behavior is not just in the provision of new injection equipment but also in the mutually respectful interactions between the participants and the staff.[21] Regulations and procedures that undermine such mutual respect—common, unfortunately, in methadone treatment today—may be the biggest potential hindrance to the effectiveness of syringe exchanges in the United States.

Summary

The sharing of injection equipment among injection drug users may be the most common source of new HIV infections in the United States.[6] Syringe exchange programs have the potential to substantially reduce HIV transmission among injection drug users. Methadone maintenance treatment, however, provides a clear example of how regulations can reduce the public health effectiveness of a controversial program for unpopular people.[19]

Avoiding the repetition of similar mistakes when regulating syringe exchange programs will require political courage, good faith, and much hard work among all involved. Neither proponents nor opponents of syringe exchange—and certainly not injection drug users, their sexual partners, and their children—will be well served by implementation of overly restricted or punitive syringe exchange programs. □

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